“Positive Pressure Ventilation During Neonatal Resuscitation In >34 Wks Gestation ;Efficacy Of LMA Vs Face Mask ; A Randomized Controlled Trial”

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MADRAS MEDICAL COLLEGE

THE TAMIL NADU DR.M.G.R.MEDICAL UNIVERSITY

CHENNAI

CERTIFICATE

This is to certify that the dissertation entitled **""Positive Pressure Ventilation During Neonatal Resuscitation In Neonates > 34 Wks Gestation ;Efficacy Of LMA Vs Face Mask ; A Randomized Controlled Trial" "** is a bonafide work done by **Dr.T.RAMESH KUMAR** during the period between AUG 2012– JAN 2013 towards the partial fulfillment of requirement for the award of D.M. (NEONATOLOGY) degree examination to be held in August 2013 by The Tamilnadu Dr.M.G.R. Medical University, Chennai.

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DECLARATION

I solemnly declare that the dissertation entitled **""Positive Pressure Ventilation During Neonatal Resuscitation In Neonates >34 Wks Gestation ;Efficacy Of LMA Vs Face Mask ; A Randomized Controlled Trial" "** is the original work done by me at the Institute of Obstetrics and Gynaecology and Hospital for women and Children, Egmore, Chennai during the D.M. course (2010-2013), under the guidance and supervision of Prof.Dr.J.Kumutha, Professor and H.O.D. of Neonatology. The dissertation is submitted to **THE TAMILNADU Dr.M.G.R. MEDICAL UNIVERSITY** towards the partial fulfillment of requirement for the award of **D.M. (Neonatology).**

Place: Chennai. (Dr.T .RAMESH KUMAR)

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CONTENTS

INTRODUCTION

The American Academy of Paediatrics has formulated the Neonatal resuscitation guidelines and published it on 2010 and suggested modification based on local needs[1]. These guidelines recommend changes in resuscitation practices from the previous guidelines formed at 2005 based on evidences rather than experience. These guidelines primarily apply to neonates undergoing transition from intrauterine to extra uterine life with difficulty. About 10% of the neonates require some form of resuscitation and less than 1% requires extensive resuscitation [2]. Ventilation of the lungs is the important step for successful resuscitation. Ineffective ventilation can lead to prolonged or unsuccessful resuscitation. Successful resuscitation needs proper anticipation, adequate preparation, accurate evaluation and prompt initiation. The first 1 minute of neonatal resuscitation is called as **golden minute** wherein active steps are taken to ventilate the lungs. Each step in resuscitation is performed for 30 seconds with assessment of heart rate, respiration and saturation at the end of every step. The decision to administer positive pressure ventilation is taken at the end of 30 seconds of starting resuscitation when the neonate is apneic or gasping or with heart rate less than 100/min. Ventilative corrective steps may be done if there is failure to rise in heart rate after initial few seconds of positive pressure ventilation. The ventilation corrective steps include mask adjustment, repositioning of baby, suctioning of oral cavity, pressure increase and usage of alternate airway like laryngeal mask airway (LMA).

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Tracheal intubation and ventilation may be done if there is failure in response to ventilation with facemask. There is no fixed criteria when to intubate and the timing of intubation may be prolonged for minutes in apneic neonates provided the heart rate is more than 100. Provision of positive pressure ventilation is usually done using facial mask in the delivery room. But face mask has certain disadvantages in administering effective ventilation. One of the common causes is air leak around the mask. Poor mask application over the face attributes to air leak. Studies from delivery room reported the median percentage of air leak with mask as 29% (0-100%) [3]. Mannequin studies reported 51% leak immediately after starting positive pressure ventilation[4].

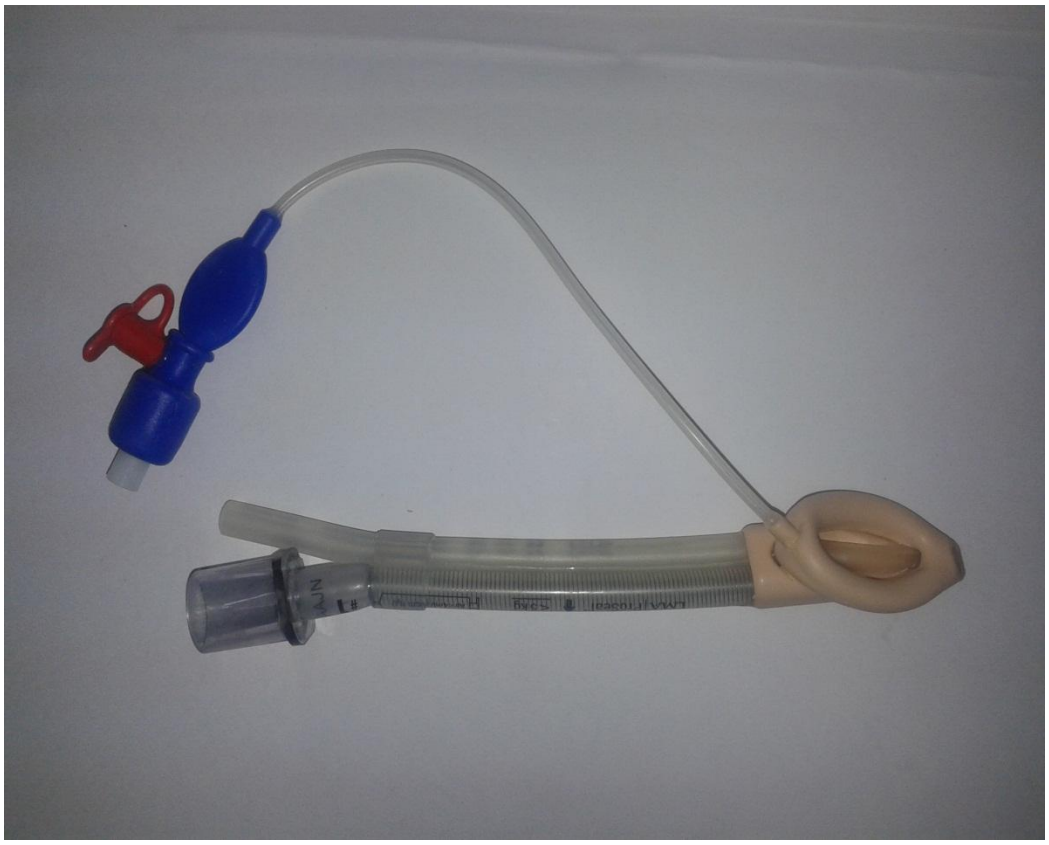
Airway obstruction is another significant factor in causing ineffective positive pressure ventilation [5]. Finer et al reported upper air way obstruction in 75% of neonates in the delivery room [6]. Manoeuvres like chin lift which is used to maintain patency of upper airway are successful only in 50% of cases [3]. Jaw thrust is the most successful method to maintain upper airway patency but it is difficult to perform with single handed facemask ventilation adding performance difficulty in mask ventilation. Mannequin studies have reported less leak in double handed versus single handed mask ventilation [7].

These setbacks might be overcome by the use of laryngeal mask airway in neonatal resuscitation. LMA requires no technical expertise, it can be inserted even by nonmedical personnel after basic training[10]. The tidal volume achieved at the lung parenchyma level is accurate for the generated pressure because leak factor plays a minimum role except at the glottis level[11].

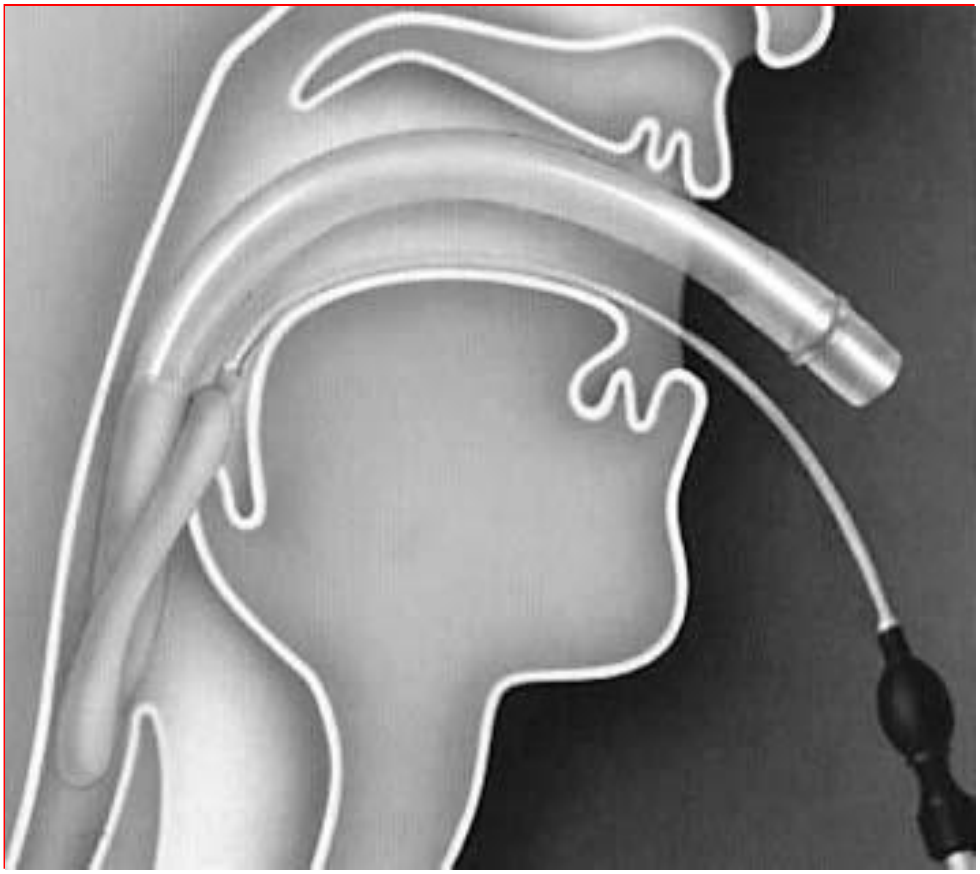
Laryngeal mask may offer certain advantage over endotracheal intubation Tracheal intubation provides effective ventilation but it needs high technical skills and leads to procedural injuries [12]. Hence a device which will not require great skill but still be effective might be the need of the hour. Alternate device like LMA overcome lack of technique and could be still be effective in ventilating the neonatal lungs.

Laryngeal mask airway was described by Archie brain as an alternative to endotracheal intubation[13]. LMA is made of medical grade silicon and withstands temperature at 125 degree for 10 minutes during autoclaving. LMA has two parts, the shaft and the airway tube. The airway tube is connected distally to the mask which is inflatable with air. The oval shaped mask is designed to snugly fit into the supra glottic area. The airway tube is attached to standard 15mm connector which can be connected to positive pressure delivering device[10].

Proseal LMA (size no 1) with Gastric vent port



Laryngeal mask airway in the Supraglottic position



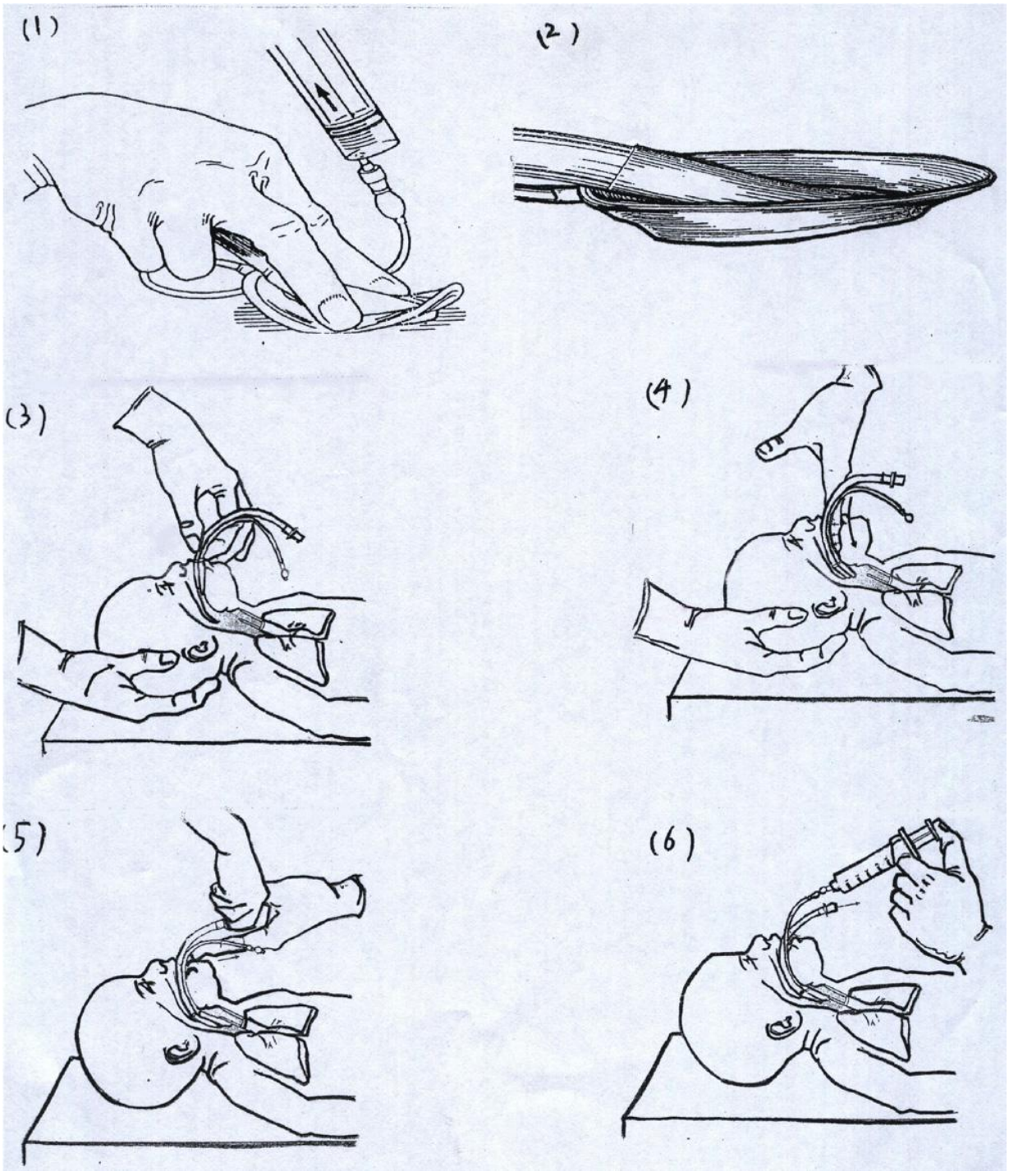
The mask portion can be inflated with air of 2-4 ml and the mask pressure can be monitored through distal port using manometer. The recommended size for neonatal use is no 1 and it can be used upto 5 kg infant. Even though the recommendations for usage is limited upto lower limit of 2 kg recent case reports have used the standard size in extremely low birth babies successfully. Five versions of LMA are available in practice in both adults and pediatric age group. But the common one used in neonates is the classic and proseal type. The proseal LMA has gastric decompression port which prevents gastric distension observed with classic LMA.

Various insertion techniques for LMA are practised. Modification of the initial description of insertion technique by Archie brain has been reported [14]. The description of insertion in neonates was extrapolated from adults as it was successful in this population.

The steps insertion technique suggested by brain is as follows[13].

- Select the suitable size–size no 1 in neonates.
- Deflate the cuff.
- Hold the LMA at the mask and shaft junction with index finger and press the tip of LMA against hard palate.
- Advance gently with one single movement using the palato pharyngeal curve.
- Continue pushing the LMA against soft palate till the tip locates in the hypopharynx.
- Inflate the mask with minimum air volume to establish adequate seal.
- Connect the proximal end to the PPV device.

Brain method of LMA insertion



The problems encountered with LMA insertion are folding of the mask inside the mouth obstructing the airway, down folded epiglottis, improper alignment of the mask with the glottis and too high placement [15-17]. The immediate complication following removal of LMA are laryngospasm, abdominal distension, stridor, vomiting, excessive salivation, coughing. The disadvantages of classic LMA are gastric insufflation and aspiration which are overcome by the newer Proseal type LMA which has gastric venting port[15] .

Apart from resuscitation LMA has been used in neonates for inter hospital transport, airway rescue in difficult situations like Pierre robin syndrome, treacher Collin syndrome, and respiratory support following failed intubation.

LITERATURE REVIEW

LMA has been used widely in paediatric and adult anaesthesia. The usage in neonatal resuscitation has been gaining popularity in the last few years. The American Academy of Paediatrics has included LMA in the neonatal resuscitation programme 2010.The Recommendation for usage of LMA as per NRP 2010 is for neonates weighing more than 2kg or Gestation age >34weeks (class 11b,LOE-B) [1]. From available evidences generated so far, the Cochrane meta-analysis [18] suggests that LMA should be used when both face mask and endotracheal intubation failed to resuscitate.

LMA offers many operative and hemodynamic advantages over face mask and endotracheal intubation. Less skills are required for LMA insertion compared to facemask and endotracheal intubation[19]. Easier placement, minimal mask leak, improved oxygen saturation, less hand fatigue, are the advantages claimed over face mask [20]. Less hemodynamic stress response reflex, avoidance of local trauma, avoidance of mal positioning of the tube in the oesophagus, insertion by trained non-medical personnel, no requirement for neuro muscular blockage are the advantages claimed over intubation[21] .

The knowledge and use of LMA in delivery room practise was studied by researchers. Trevisanuto et al reported 23% of the paediatricians have experience with LMA for airway management in neonates [22]. Similarly Gandhini studied the knowledge of LMA in health care

professionals and reported 57% of the studied population did not know the use of LMA in neonatal resuscitation[23] .

Mannequin studies suggest that proficiency in LMA insertion technique can achieved within 15 minutes of education session[24].

Zonardo studied the knowledge gained by mannequin based training of LMA to physicians and midwifes and reported post training higher knowledge and ease to insert LMA successfully in both groups [24].

The first prospective study of LMA in neonates was done by Paterson et al[25]. They demonstrated successful insertion of LMA with first attempt in all the 21neonates studied and 20/21 neonates were successfully resuscitated.

Observational study by Trevisanuto et al compared 95 neonates >34 gestational age receiving resuscitation with LMA with historical control group[12]. The successful resuscitation with LMA was 99% in the study .The rate of intubation when compared to historical control reduced from 67-34% over 4 years from the study.

Observational study by Gandhini and Brimacombe analysed 104 neonates requiring positive pressure ventilation during resuscitation and reported successful insertion with first attempt in all cases and successful resuscitation in 103/104 neonates[26].

Zonardo reported resuscitation of late preterm using LMA was associated with lower NICU admission and shorter length of stay

compared to face mask or intubation [27]. High APGAR scores, less respiratory support were observed when compared to neonates receiving endotracheal intubation.

So far 4 RCTs have been done in usage of LMA in neonatal resuscitation. 2 studies directly compared face mask with LMA whereas the third used intubation vs. LMA and the fourth compared all the three devices.

Singh et al compared LMA VS face mask in 50 neonates with gestational age >35 weeks or birth weight >1500gin the delivery room[28]. The study could not find any difference between intubation rates, successful resuscitation rates and APGAR between two groups. The sequence generation, allocation concealment, and blinding were uncertain in the study.

Zhu et al randomised 369 neonates >34 weeks or > 2 kg to receive ventilation with LMA or face mask soon after birth[29]. Classic LMA was used in the study. The LMA group had successful resuscitation ($p < 0.001$) and short response time to insert the device ($p < 0.001$) and shorter ventilation time when compared to face mask group. Face mask had higher tracheal intubation rate when compared to LMA. At low Apgar score 4 OR 5 at 1 minute the successful resuscitation with LMA was higher than with face mask ($p<0.01$). At APGAR score of 6 or 7 at 1 minute there was no significant difference in successful resuscitation between the groups. There was no significant difference in the incidence of gastric regurgitation. The success rate of first attempt (98.5%) and

successful resuscitation rate was (99%) high in the LMA group. The author suggested LMA has important role in neonatal resuscitation.

The disadvantage of the study is that it didn't provide consort chart or consent process obtained in the study and the method of blinding was not reported.

RCT done by Esmail et al randomized LMA and endotracheal intubation during neonatal resuscitation in 40 neonates and found no significant difference in respiratory outcomes[30]. The insertion time was shorter in the ET group when compared to LMA. Grein reported the difference in insertion time is due to operator difference wherein the intubation group was performed by anaesthetist and the LMA group was done by paediatricians[18]. The study is subject to bias in enrolment, allocation and outcome measurement.

Feroze et al compared LMA VS ET tube vs Face mask ventilation in 75 neonates more than 1500 grams[31].The anaesthesia trainee were involved in this study. The success rate with LMA resuscitation was 95% compared to 90% in face mask and 80% intubation group. The no of attempts used for LMA insertion was 1-2 whereas it was 2- 3 in the facemask group. The mean time taken to insert the device was 9 sec compared to 9.5 seconds with face mask. The drawback of the study is that the randomisation sequence generation is not clear and the blinding and allocation concealment was uncertain.

The performance of the different types of LMA has been studied. Micaglio compared Proseal and classic LMA and found higher rate of successful first attempt insertion with Proseal LMA without much change in insertion time[32].

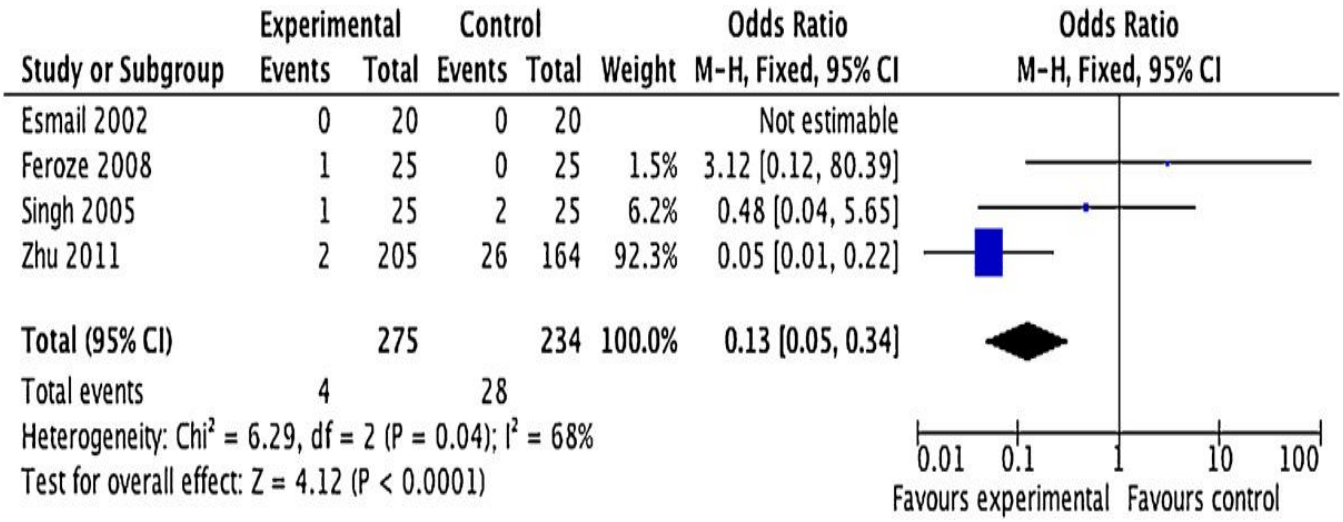
Classic LMA produces less targeted tidal volume at higher pressure due to poor seal when compared to Proseal LMA [33]. This is overcome by Proseal LMA which forms good seal around the glottis even at higher positive pressure ventilation.

Micaglio observed the peak inflation pressure delivery was similar between classic and proseal LMA at mask pressure of 10-20 cm H_2o. With higher inflation pressure the classic LMA could not achieve the targeted pressure. Proseal operates in delivering the desired tidal volume at high positive pressure ventilation providing adequate supra glottic seal.

Apart from resuscitation LMA has been recently used in many special situations like surfactant administration, prolonged ventilation and neonatal transport [34]. Study done with surfactant administration via LMA in preterms reported low fio2 requirements, low CPAP failure compared with surfactant administered via ET. The current available evidences suggest that surfactant administration via LMA should be limited to clinical trials. LMA offers significant advantage over ET intubation during air transport by reducing the requirement of sedatives

in the LMA group. LMA has been used for ventilation for prolonged period’s upto 6 days without complications. Metanalysis of the 4 RCTs done by schmolzer suggest LMA is feasible and safe alternative to mask ventilation in infants more than 34 weeks and birth weight more than 2kg[34]. Further RCTs are recommended before using LMA as a standard of care in neonatal resuscitation.

Forest plot showing Metaanalysis of RCTs



HYPOTHESIS

Positive pressure ventilation with laryngeal mask airway reduces the need for subsequent intubation when compared to ventilation with Face mask during Resuscitation in Neonates >34 weeks gestation age.

AIMS AND OBJECTIVES

To compare the efficacy of LMA versus Face mask ventilation in reducing the need for endotracheal intubation during neonatal resuscitation.

OUTCOME OF THE STUDY

Primary Outcome

- Total number of neonates requiring endotracheal intubation

Secondary outcome

- Duration of positive pressure ventilation
- Time taken for insertion of the device
- Time taken to reach Heart Rate > 100
- No of attempts made to insert
- Apgar score at 1 and 5 minutes
- Complications of the device

METHODOLOGY

Study Centre

Tertiary Care Centre, Chennai.

Duration of the Study

April 2012 to December 2012

Study Design

Prospective quasi randomised controlled trial

Material & Methods

The Randomised trial was carried out at the delivery room and operation theatre of Institute of Obstetrics & Gynecology Egmore, a tertiary care Govt. Maternity Hospital in Chennai, Tamilnadu.

Inclusion Criteria

Neonates born at >34 weeks of gestation as per LMP/USG taken from first trimester and expected Birth weight more than 2 kg who require positive pressure ventilation will be included .The indications for PPV are

- Apnea or
- Poor respiratory effort /Gasping or
- HR <100 after 30 seconds of initial resuscitation (AAP 2010 Guide lines)

Exclusion Criteria

- Non vigorous babies born through meconium stained amniotic fluid needing PPV
- Those babies with life threatening congenital anomalies of the respiratory system, congenital heart disease incompatible with life (antenatal diagnosis) will be excluded from the study

Sample Size

Based on previous study by Xio yu zhu et al 2011 from china, the success rate of resuscitation with LMA was 15% higher than done with face mask. Based on that study to give power of 90% and an alpha error of 0.05 the sample size was calculated to be 71 on each limb.

Randomization and Stratification

The randomization sequence was generated by computer generated number which included blocks of equal sizes. Each week constituted one block labelled to administer either LMA or face mask in sealed envelope. The investigator was blinded to the sequence. Out of 40 blocks generated 24 only was used in the study with 13 blocks in LMA group and 11 blocks in the face mask group.

Methodology

Proseal type of Laryngeal mask airway size 1 (the laryngeal mask company limited, lerocher, victoria) was used for study purpose. The LMA is reusable one and sterilized by autoclaving at 120 c for 10 minutes. It can be reused upto 40 times. The LMA was used both in the delivery room, emergency and elective theatre. The investigator was trained in LMA insertion by pediatric anesthetist the participants in the study were paediatric residents who were posted for resuscitation and trained by the investigator. They were appraised about NRP guidelines. Subsequently LMA insertion was practised in mannequin. 10 successful insertions of LMA were the criteria for allowing them to participate in the study. All the participants were able to successfully insert LMA in the mannequin supervised by the investigator.

The information regarding the device to be used to the participants was conveyed through posters displayed in the delivery room and operation theatre .the display was changed every week depending on the randomization. Stop clock with analog was used to monitor the progress of resuscitation. The outcome measures were filled in the proforma and the PPV delivered babies were followed up in the initial 24 hours for complications.

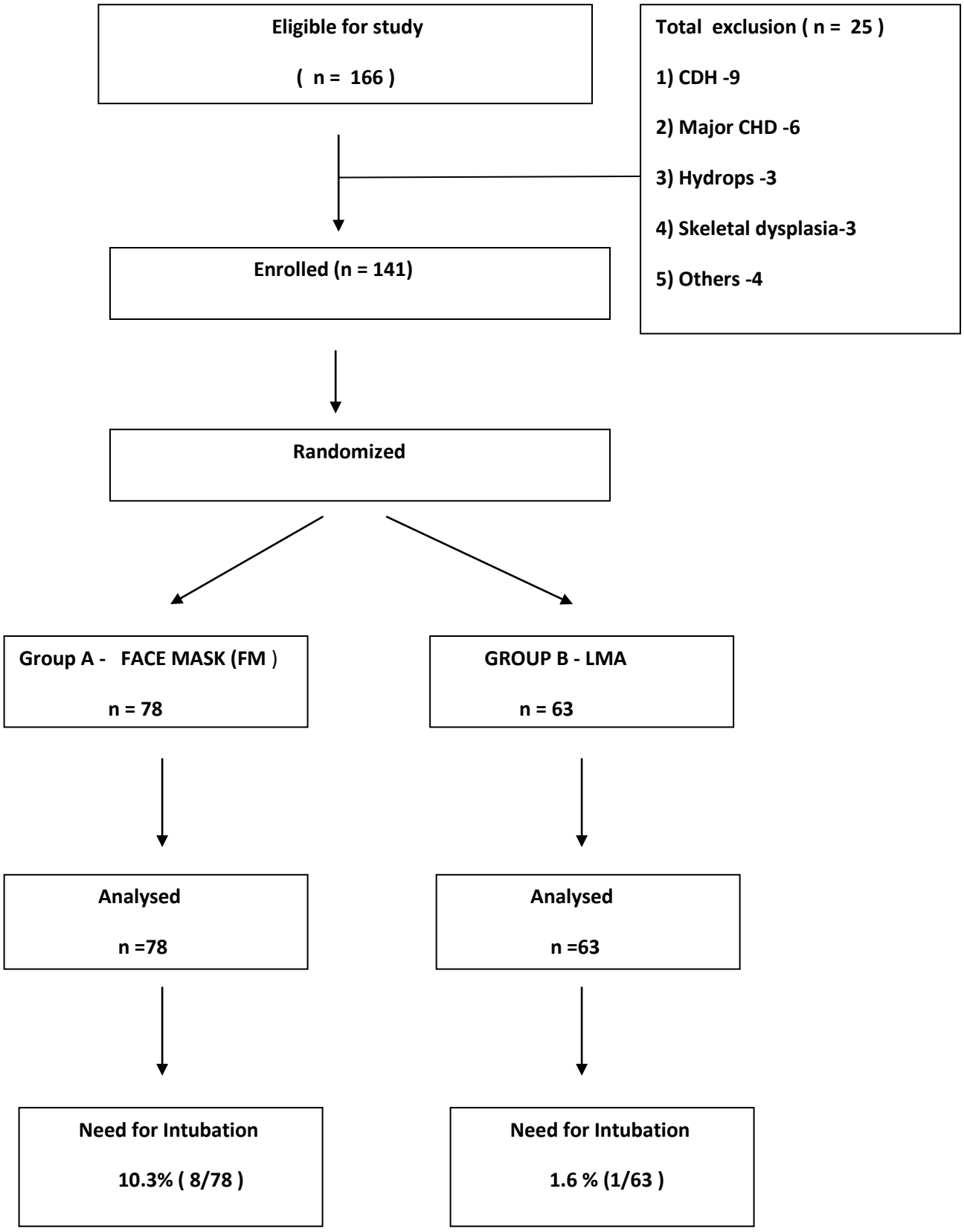
Data Collection and Methods

Data was collected in the prescribed proforma.

Statistical analysis

Continuous variables were analysed by mean standard deviation and categorical data were analysed by chi square test. Fischer extact test was used to obtain statistical significance (P value). Relative risk was calculated for outcome variable and confidence value estimated. SPSS 17 software was used for data analysis.

Randomization chart



RESULTS

Base Line Characteristics between Groups

Table 1

Characteristics	Face Mask (n=78)	LMA (n=63)	P
Gestational age Mean ± SD	38.53 ±2.050	38.53±1.998	0.981
Birth weight Mean ± SD	2858.31 ±538.36	2818±556.033	0.669
SGA LGA	4 (5.1)* 10(12.8)	5 (7.9) 7 (11.1)	0.849
Gender Male Female	 35 (44.9) 43 (55.1)	 34 (54) 29 (46)	0.283
Gravida Primi Multi	 51 (65.4) 27 (34.6)	 45 (71.4) 18 (28.6)	0.444
Mode of delivery Labour naturalis Caesarean Vaccumdelivery Assisted breech Forceps	 32 (41) 37 (47.4) 5 (6.4) 2 (2.6) 2 (2.6)	 18 (28.6) 36 (57.1) 4 (6.3) 4 (6.3) 1 (1.6)	0.480

* number in brackets expressed as percentage

The baseline characteristics like birth weight, gestational age, intrauterine growth, gender, gravida, mode of delivery were comparable between groups.

Comparison of Perinatal Risk Factors between Groups

Table 2

Characteristics	**Face Mask (n=78)**	**LMA (n=63)**	**P**
Maternal anaemia	10 (20)*	10 (20)	1.00
Maternal hypertension	8 (10.3)	11(17.5)	0.21
Diabetes	5 (6.4)	2 (3.2)	0.460
Placental abruption	3 (3.8)	1 (1.6)	0.628
Maternal drugs	6 (7.7)	13 (20.7)	0.040
Maternal sepsis	8 (10.3)	1 (1.6)	0.042

* number in brackets expressed as percentage

Except for the maternal drug administration and maternal sepsis the remaining perinatal risk factors didn't show any statistical significance between groups

Reason For Initiating Positive Pressure Ventilation

Table 3

Reason for initiating PPV	Group A Face Mask	Group B LMA	P¥
Apnea	53 (67.9)*	48 (76.2)	0.320
Gasping	20 (25.6)	14 (22.2%)	
Heart rate < 100	5 (6.4)	1 (1.6%)	

* number in brackets expressed as percentage

¥ fischer exact test

The reason for initiating ventilation at 30sec following initial steps was comparable between groups.

Primary Outcome

Table 4

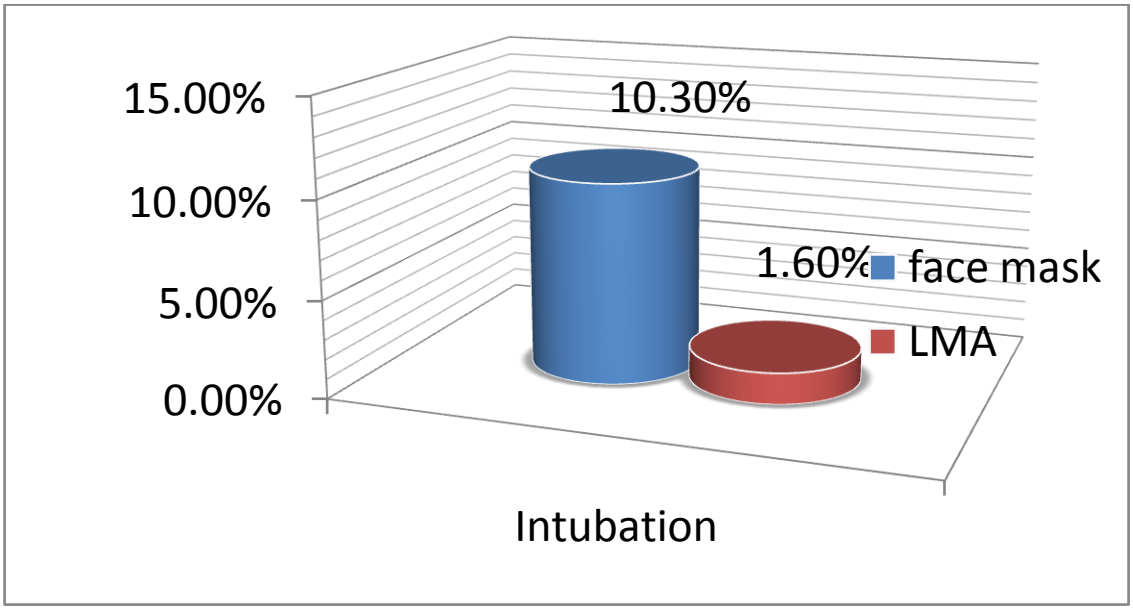
Outcome	Group A Face mask	Group B LMA	P¥
Intubation	8 (10.3)	1 (1.6)	0.042

* number in brackets expressed as percentage

¥ fischer exact test

The primary outcome (i.e.) need for intubation or failure of PPV is presented in table 4. Total 10.3% (n= 8) of neonates in the face mask group required intubation as compared to 1.6% (n= 1) in the LMA group which was statistically significant (p =0.04).

COMPARISON OF PRIMARY OUTCOME



Inferential Statistics

Table 5

Outcome	Group A Face mask	Group B LMA	Relative risk	95% CI for RR	P¥
Intubation	8 (10.3)	1 (1.6)	7.086	0.862-58.3	0.069

* number in brackets expressed as percentage

¥ fischer exact test

Face mask is 7 times risk for intubation compared to LMA ,with wide confidence interval and the value falls below 1 which is not statistically significant.

Reason for tracheal intubation

Table 6

Reason for tracheal intubation	Group A Face mask	Group B LMA	p¥
Failure of PPV	6 (66.7)*	1 (11.1)	0.999
Prolonged ventilation	2 (22.2)	0	

* number in brackets expressed as percentage

¥ fischer exact test

The reason for initiating ventilation at 30 sec following initial steps was comparable between groups.

Secondary Outcome

Duration of PPV

Table 7

Outcome	Group A Face mask	Group B LMA	P[¥]
Duration of PPV	78 (58.9)* ± 41.5	63 (60.6) ± 34.7	0.797

* number in brackets expressed as percentage

[¥] fischer exact test

The mean duration of PPV in the face mask group was 58.87 seconds (n=78) and 60.56 sec (n= 63) in the LMA group (p = 0.797) .

Post natal age at intubation

Table 8

	Group A Face mask	Group B LMA	Standard deviation
Post natal age at intubation	6 (80.8)*	1 (120)	47.373

* number in brackets expressed as mean duration in seconds

The mean duration at which intubation was done in neonates, where prolonged PPV was continued for persistent apnea was 80.8 sec in the face mask group and 120 sec in the LMA group.

Time taken to insert the device

Table 9

Outcome	Group A Face mask	Group B LMA	P
Time taken to insert the device	13 (2.31)* ± 0.9	23 (2.9) ± 2.1	0.26

* number in brackets expressed as mean duration in seconds

The mean time taken to insert the device was 2.31 sec in the face mask group and 2.87 sec in the LMA group (p= 0.25).

Time taken to reach HR >100

Table 10

Outcome	Group A Face mask	Group B LMA	P¥
Time taken to reach HR >100	64 (13.6)* ± 20.9	48 (10.3) ± 14.5	0.35

* number in brackets expressed as percentage

The time taken to reach heart rate more than 100 after ventilation was lower in the LMA group was 10.25 sec as compared to face mask group 13.55sec (p=0.35).

No of attempts made to insert

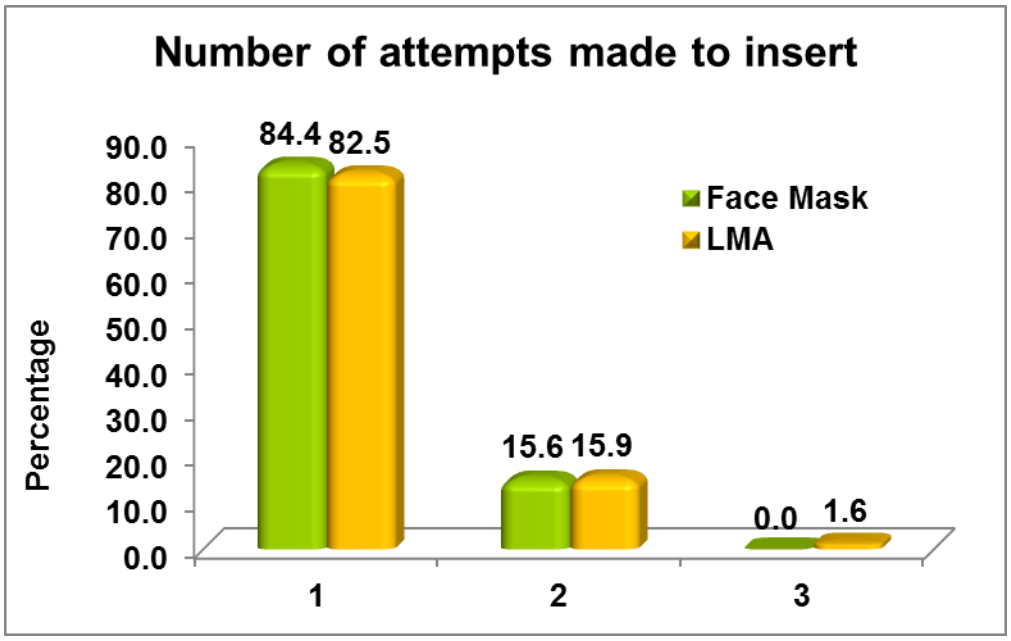
Table 11

No of attempts made to insert	Group A Face mask	Group B LMA	P¥
1	65 (84.4)*	52 (82.5)	0.72
2	12 (15.6)	10 (15.9)	
3	0	1 (1.6)	

* number in brackets expressed as percentage

¥ fischer exact test

83.3% (n=65) in the face mask group and 83.8% (n=52) in the LMA were successfully resuscitated in the first attempt (p=0.72). Insertion of the device by second attempt was higher in the LMA group when compared to face mask group.


Number of attempts made to insert
Percentage
90.0
80.0
70.0
60.0
50.0
40.0
30.0
20.0
10.0
0.0
84.4
82.5
15.6
15.9
0.0
1.6
1
2
3
Face Mask
LMA

Requirement for Chest Compression

Table 12

Outcome	Group A Face mask	Group B LMA	P[¥]
Chest compression	3 (3.8)	0	0.25

* number in brackets expressed as percentage

¥ fischer exact test

3.8 % (n=3) of the failure case in the face mask group required chest compression as against no case in the LMA failure group (p=0.25).

Apgar Score — Successful Resuscitation Ratio

Table 13

outcome	2-3		4-5		6-7	
	LMA n =25	FM n=32	LMA n =22	FM n=24	LMA n =12	FM n =28
Successful resuscitation ratio	24 (96)	25 (78.1)	22 (100)*	23(95.8)	12 (100)	28(100)

* number in brackets expressed as percentage

The successful resuscitation in both groups in comparison with APGAR scores were analysed .LMA has higher successful resuscitation (96%) rate at low APGAR score of 2-3 when compared to face mask (76%) (p=0.598). At higher APGAR there was no difference between groups.

Complications of the Device

Table 14

outcome	Group A Face mask	Group B LMA	P¥
Complications	10 (12.8)	3 (4.8)	0.1

* number in brackets expressed as percentage

¥ pearson chi square test

12.8 % (n=10) of the neonates in the face mask group had complication when compared to 4 % (n=3) in the

LMA group which was not statistically significant (p= 0.1).

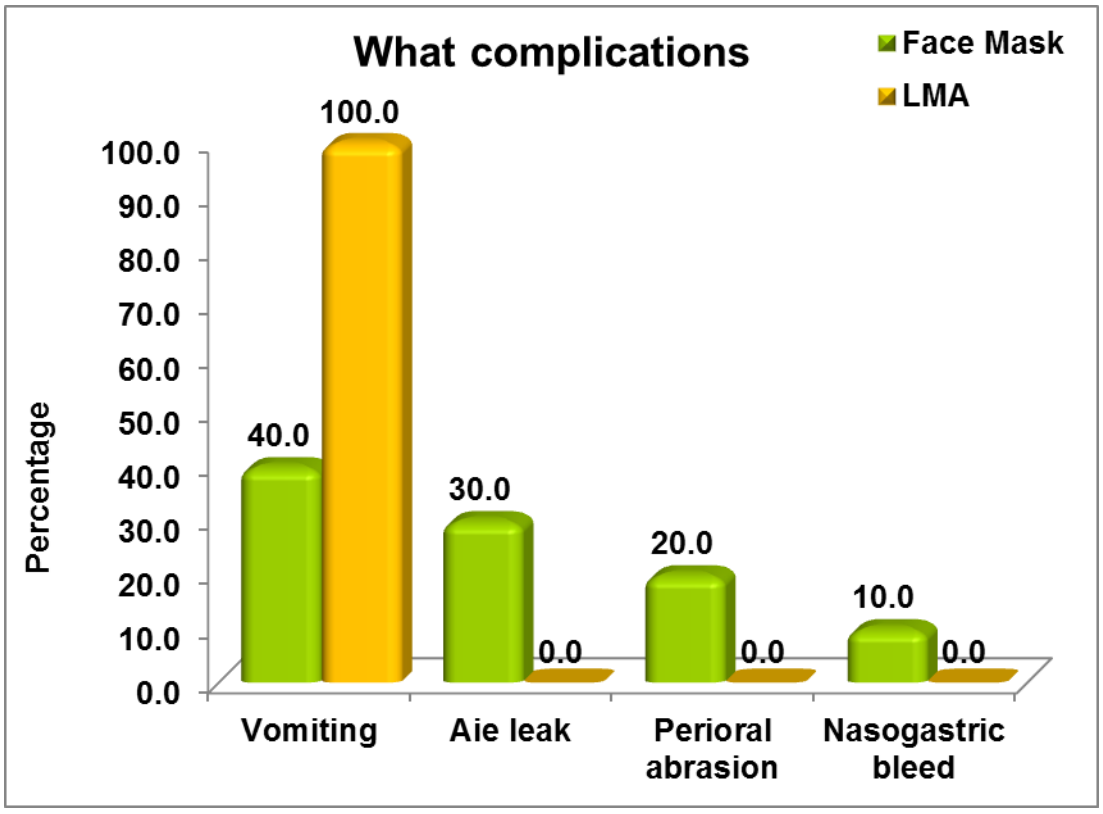
Table 15

Complications	Group A Face mask	Group B LMA	P¥
Vomiting	4 (40)	3 (100)	0.49
Air leak	3 (30)	0	
Perioral abrasion	2 (20)	0	

* number in brackets expressed as percentage

¥ fischer exact test

Facial abrasions (20%), vomiting and air leak (30%) were the complications seen in the face mask group. LMA group had vomiting as the complication (p =0.486).


What complications
Face Mask
LMA
Percentage
100.0
90.0
80.0
70.0
60.0
50.0
40.0
30.0
20.0
10.0
0.0
40.0
100.0
30.0
0.0
20.0
0.0
10.0
0.0
Vomiting
Aie leak
Perioral abrasion
Nasogastric bleed

Mortality And Morbidity

survival

Table 16

Outcome	Group A Face mask	Group B LMA	P[¥]
Survival	74 (94.9)	61 (96.8)	0.69

* number in brackets expressed as percentage

¥ fischer exact test

96.8% (n=61) in the LMA group survived as compared to 94.9 % (n=74) in the face mask group. Death was higher in the face mask group compared to LMA group (p=0.692).

Mortality And Morbidity

Need for Ventilation

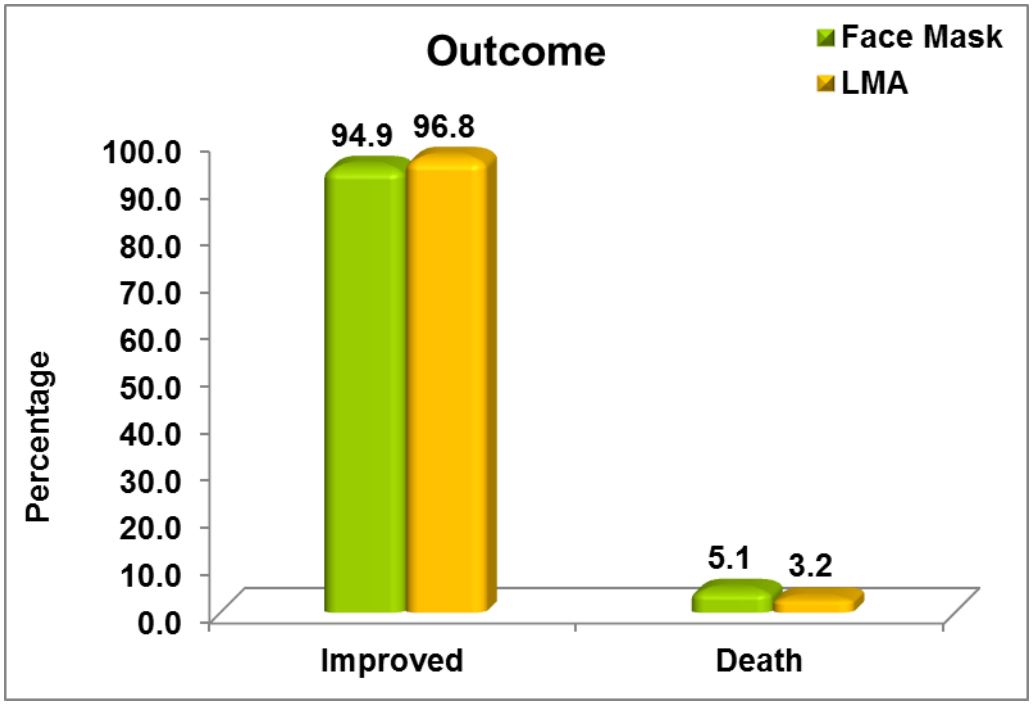
Table 17

Outcome	Group A Face mask	Group B LMA	P[¥]
Need for subsequent ventilation	7 (9)*	4 (6.3)	0.75

* number in brackets expressed as percentage

¥ fischer exact test

9% (n=7) of the neonate in the face mask group required ventilation in the post resuscitative phase compared to 6.3% (n=4) in the LMA group for various reasons which was not statistically significant (p=0.75)


Outcome
Face Mask
LMA
Percentage
100.0
90.0
80.0
70.0
60.0
50.0
40.0
30.0
20.0
10.0
0.0
94.9
96.8
5.1
3.2
Improved
Death

Mortality and Morbidity -

Incidence of HIE

Table 18

Incidence of HIE	Group A Face mask	Group B LMA	P¥
HIE 1	2 (2.6)*	0	0.99
HIE 2	5 (6.4)	1 (1.6)	
HIE 3	4 (5.1)	1 (1.6)	

* number in brackets expressed as percentage

¥ fischer exact test

The incidence of HIE was higher in the facemask group. HIE 1 - 2.6% (n =2) , HIE 2 - 6.4% (n=5), HIE -5.1% (n=4) in the facemask group and HIE 1 - 0%, HIE 2 - 1.6 % (n=1), HIE 3-1.6% (n=1) in the LMA group.

Mortality and Morbidity - Respiratory Morbidity

Table 19

Respiratory morbidity	Group A Face mask	Group B LMA	P¥
RDS	1 (1.3)*	1 (1.6)	0.99
TTN	6 (7.7)	2 (3.2)	

Respiratory morbidities included RDS which was similar between groups while TTN was observed more in the face mask group. (p =0.99)

Mortality and Morbidity - Incidence of Sepsis

Table 20

Sepsis	Group A Face mask	Group B LMA	P¥
EOS	1 (1.3)*	2 (3.2)	0.4
LOS	2(2.6)	0	

* number in brackets expressed as percentage

¥ fischer exact test

The incidence of late onset sepsis was high but not statistically significant .incidence of EOS was high in the LMA group.(p =0.4)

DISCUSSION

This single centre randomised control trial was designed to compare efficacy of Face mask vs LMA in neonates >34 weeks gestation during neonatal resuscitation. Out of 1850 neonates eligible for the study 141 neonates were included and randomized to 78 neonates in the facemask group and 63 in the LMA group. The baseline characteristics like age, gestational age, mode of delivery were comparable between groups. The perinatal risk factors like drug intake, maternal sepsis were not comparable. (P=0.04). The RCTS done by Singh et al and Feroze et al included 50 neonates while observational study done by Gandhini included 104 neonates. Zhu et al included 369 neonates which is the study done so far with large number of samples. Zhu compared face mask and LMA and observed 15% efficacy in outcome between groups .The sample size in our study was calculated based on the effect size observed by Zhu et al.

The LMA insertion technique used in the study was modified from classic brain technique used in adults and pediatric age groups. The mask portion of the LMA was partially filled with air before insertion to avoid delay in starting PPV. The LMA was held at the airway tube 2 cm above the mask and inserted using the palatopharyngeal curve. This technique could avoid unnecessary posterior pharyngeal wall stimulation and the reflex brady cardia. We did not observe any major complications like obstruction by the device, brady cardia, epiglottic down folding or laryngospasm with this technique.

We randomized the groups into single week .Each week constituted one block labelled to administer either LMA or face mask in sealed envelope. Zhu et al randomized groups based on even and odd dates.The sequence generation and allocation concealment were uncertain in the RCT done by Esmail and Feroze and Singh et al.

Neonates with gestational age >34 weeks were included in our study. Study done by **Singh** et al and **Esmail** et al included >35 weeks with birth weight more than 1.5 kg. Observational study by **Zonardo** included neonates between 34-37 week gestation. We observed more number of neonates with LGA (12.8%) compared to SGA (5.4%) when plotted in the AIIMS chart used in our study. This growth assessment was not compared in previous studies. Among the failure cases (n=9) both the SGA and LGA were equally distributed.

This is the first clinical trial in neonatal resuscitation using proseal LMA in neonatal resuscitation. **Zhu** et al used classic LMA and found high successful resuscitation rates .He also observed regurgitation and vomiting as the adverse event [(29)]. We did not observe any regurgitation or aspiration with proseal LMA in our study.

Study by Zhu et al randomized 205/369 the LMA group compared to 164/369 in the face mask group .The participants in the Zhu study were paediatricians with 3 years experience in neonatology while in our study the participants were residents with 2 months experience in neonatal care.

Blinding of participants, personnel, and outcome measures in all the RCT done on neonatal resuscitation were uncertain from met analysis done by schmolzer. In our study blinding of the device to the participants was not possible but the

participants were blinded to the randomization sequence and the outcome measures.

We observed higher intubation rate in the face mask group compared to LMA group which was statistically significant. 10.6% needed intubation compared to 1.6% in the LMA group. Intubation was done when there is failure of the device and for prolonged ventilation. Failure of device is defined by failure to increase in heart rate with 30 seconds of PPV and prolonged ventilation defined as need for respiratory support for 5min with heart rate more than 100/bpm. 85% (n =6) neonates needed intubation due to failure of the device compared to 15% (n=1) in the LMA group which showed ineffective tidal volume delivery in the face mask group. **Zhu** observed 14.87% difference in the intubation rates between groups. We observed 8.7% difference in intubation between groups which was statistically significant. **Finer** et al reported higher mask leak percentage during the initial 2 minutes of resuscitation with face mask leading to ineffective ventilation.

Observational study by Trevisanuto et al studied 94 neonates and observed the median duration of PPV by LMA as 74 seconds which is high compared to our study. Zhu et al observed less PPV duration in the LMA group with mean of 36.4 sec compared to 66.2 sec in the face mask group. The mean duration of positive pressure ventilation in face mask group was 58.9 seconds compared to 60.6 sec in the LMA group in our study. This could be attributed to the indecision regarding the timing of discontinuation of PPV with LMA. Since cry as an assignment sign is not possible in LMA group this group might have received PPV for prolonged duration. We observed very short time (mean-2.8 sec) to insert both the devices when compared to various studies where the mean is 9 sec.

The time taken to increase the heart rate following positive pressure ventilation is shorter with LMA (10.3 sec) in our study compared to 13.6 sec in the face mask group which indicates effective ventilation with LMA.

The rate of first attempt of successful insertion of the device was similar between the groups and the total percentage of insertion with both the device were low in our study compared to previous studies[29].The no of second attempt was high in LMA and third attempt of insertion was high in the face mask group .the first attempt successful insertion rate with LMA (98.5%) studied by Zhu et al is high compared to our study (82.5%) .The difference in operator experience could have influenced the outcome.

The requirement of chest compression is observed only with face mask due to inadequate tidal volume from ineffective ventilation. **Schmolzer** suggested the usage of respiratory monitor during resuscitation to assess the leakage ,air way obstruction and the tidal volume delivered [34].

The successful resuscitation rate of LMA with low Apgar score was high compared to face mask and similar at high APGAR scores. In the facemask group we observed higher requirement for subsequent ventilation in the post resuscitative phase. The incidence of hypoxic ischemic encephalopathy was also high in the face mask group compared to LMA but statistical significance was not observed. **Trevisanuto** observed improved hemodynamic stability with insertion and increased oxygen saturation with LMA [10] .

The gastric insufflation and aspiration were not observed in any of the cases in our study. Gastric venting was done through the side port of the proseal LMA after insertion. Complication like oral bleeding, airleak, perioral abrasion was noted in the face mask which were not seen with LMA. Lubrication offered by

oral secretion and the soft silicon material of the proseal LMA minimises damage during insertion. We observed increased percentage of clinical sepsis in the face mask group compared to LMA group.

96.8% of the neonates survived in the LMA group compared to 94.9% in the face mask group.12.8% (n=10) in the face mask group needed admission whereas only 3.2% (n=2) neonates in the LMA group needed NICU admission. Observational study by **Trevisanuto** reported 25.6% of the LMA group needed NICU admission compared to 32.4% in the face mask group and no death in both groups.

LMA is a safe alternative to face mask in neonatal resuscitation. The statistical significance of less need for intubation observed in our study with LMA suggest it as a suitable device to provide PPV substituting face mask .Also the usage of LMA can be expanded in areas where technical difficulty is encountered with face mask application .This applies to neonatal transport done by emergency technicians and in primary health centres where resuscitation are done by trained staff nurses.

Limitations of The Study

This study was done with paediatric residents who had no previous experience with LMA compared to face mask in neonatal resuscitation

We didn’t use objective parameters like pressure measurement using manometer, respiratory function monitor to assess efficacy of ventilation which is more reliable.

Even though the outcome measures were blinded the blinding of the participant to the device was not practically possible.

Inferential statistics showed lack of significance with wide confidence interval in the primary outcome measures and hence cannot be extrapolated to the population for recommendations.

Conclusion

The role of LMA in neonatal resuscitation when compared to facemask is efficacious and statistically significant.

LMA quickly restores the heart rate to more than 100 when compared to face mask.

Average time taken to insert LMA is less than 3 seconds even when done by paediatric residents with training. Hence use of LMA is not associated with any delay in initiation of resuscitation.

The mean duration of PPV by LMA is comparable to facemask. LMA may be applied in situations where prolonged PPV is needed as a substitute to face mask ventilation.

Further studies in the use of LMA in neonatal resuscitation are required for recommending changes in clinical practice.

LMA is a safe and more effective alternative to face mask in neonatal resuscitation

Bibliography

1. Perlman, J.M., et al., *Part 11: Neonatal resuscitation: 2010 International Consensus on Cardiopulmonary Resuscitation and Emergency Cardiovascular Care Science With Treatment Recommendations.* Circulation. **122**(16 Suppl 2): p. S516-38.

2. *Wyllie, J., et al., Part 11: Neonatal resuscitation: 2010 International Consensus on Cardiopulmonary Resuscitation and Emergency Cardiovascular Care Science with Treatment Recommendations. Resuscitation. **81 Suppl 1**: p. e260-87.*

3. Schmolzer, G.M., *Airway obstruction and gas leak during mask ventilation of preterm infants in the delivery room.* Arch Dis Child Fetal Neonatal Ed, 2011. **96**: p. 254-257.

4. donnell, o., *neonatal resuscitation a model to measure inspired and expired tidal volume and assess leakage at the face mask* arch diseases in child fetal and neonatal, 2005. **90**: p. f388-91.
5. chua, c., *airway manouer to achieve upper airway patency during mask ventilation in newborn infants.* Resuscitation, 2012. **83**: p. 411-416.

6. Finer, N.N., *Airway obstruction during mask ventilation of very low birth infants during neonatal resuscitation* Pediatrics, 2009. **123**: p. 865-9.

7. Tracy, *Mask leak in one person mask ventilation compared to two person in newborn infant manikin study.* Arch Dis Child Fetal Neonatal Ed, 2010.

8. Kattwinkel, J., *ILCOR Advisory statement ;resuscitation of the newly born infant* pediatrics, 1999. **103 e 56**.

9. Trevisanuto, D., *cardiopulmonary resuscitatio in the newborn.* springer, 2001(16-20): p. 1165-74

10. Trevisanuto, D., et al., *The laryngeal mask airway: potential applications in neonates.* Arch Dis Child Fetal Neonatal Ed, 2004. **89**(6): p. F485-9.

11. Brimacombe, J., *the laryngeal mask airway;anatomical and physiological implications* Acta Anaesthesiol scand, 1996. **40**: p. 201-9.

12. Trevisanuto, D., et al., *Laryngeal mask airway: is the management of neonates requiring positive pressure ventilation at birth changing?* Resuscitation, 2004. **62**(2): p. 151-7.

13. Brain, *The laryngeal mask airway -a new concept in airway management.* Br J Anaesth 1983. **55**: p. 801-5.

14. alici, h.a., *A new technique of laryngeal mask airway insertion in a newborn with pierre -robin syndrome-case report.* The eurasian journal of medicine, 2008. **40**.

15. Brimacombe, J., *The laryngeal mask airway -limitations and controversies.* Int Anesthesiol Clin, 1998. **1998**(36): p. 155-82.

16. Brimacombe, J. and D. Gandini, *The laryngeal mask airway: potential applications in neonatal health care.* J Obstet Gynecol Neonatal Nurs, 1997. **26**(2): p. 171-8.

17. schmiesing, *An airway management device -The laryngeal mask airway ; review.* J intensive care med 1998. **13**: p. 32-43.

18. Grein, A.J. and G.M. Weiner, *Laryngeal mask airway versus bag-mask ventilation or endotracheal intubation for neonatal resuscitation.* Cochrane Database Syst Rev, 2005(2): p. CD003314.

19. Martin, *training nursing staff in airway management for resuscitation - clinical comparison of facemask and laryngeal mask.* Anaesthesia, 1993. **18**: p. 33-7.

20. Watcha, *laryngeal mask airway vs facemask and guedal airway during pediatric myringotomy.* Arch otolaryngol head neck surg, 1994. **120**: p. 877-80.

21. Fujii, *circulatory response to laryngeal mask airway insertion or tracheal intubation in normotensive and hypertensive patients.* Can J Anaesth, 1995. **42**: p. 32-6.

22. Trevisanuto, D., et al., *Laryngeal mask airway in neonatal resuscitation: a survey of current practice and perceived role by anaesthesiologists and paediatricians.* Resuscitation, 2004. **60**(3): p. 291-6.

23. Gandini, D. and J. Brimacombe, *Manikin training for neonatal resuscitation with the laryngeal mask airway.* Paediatr Anaesth, 2004. **14**(6): p. 493-4.

24. Zanardo, V., et al., *Laryngeal Mask Airway for neonatal resuscitation in a developing country: evaluation of an educational intervention. Neonatal LMA: an educational intervention in DRC.* BMC Health Serv Res. **10**: p. 254.

25. Paterson, S.J., et al., *Neonatal resuscitation using the laryngeal mask airway.* Anesthesiology, 1994. **80**(6): p. 1248-53; discussion 27A.

26. Gandini, D. and J.R. Brimacombe, *Neonatal resuscitation with the laryngeal mask airway in normal and low birth weight infants.* Anesth Analg, 1999. **89**(3): p. 642-3.

27. Zanardo, V., et al., *Delivery room resuscitation of near-term infants: role of the laryngeal mask airway.* Resuscitation. **81**(3): p. 327-30.

28. Singh, R., *Controlled trial to evaluate the use of laryngeal mask airway* j anesthesiol clin pharmacol 2005. **21**: p. 303.

29. Zhu, X.Y., et al., *A prospective evaluation of the efficacy of the laryngeal mask airway during neonatal resuscitation.* Resuscitation. **82**(11): p. 1405-9.

30. Esmail, *Laryngeal mask airway versus endotracheal intubation for APGAR score improvement in neonatal resuscitation.* Egypt J Anaesth, 2002. **18**: p. 115-21.

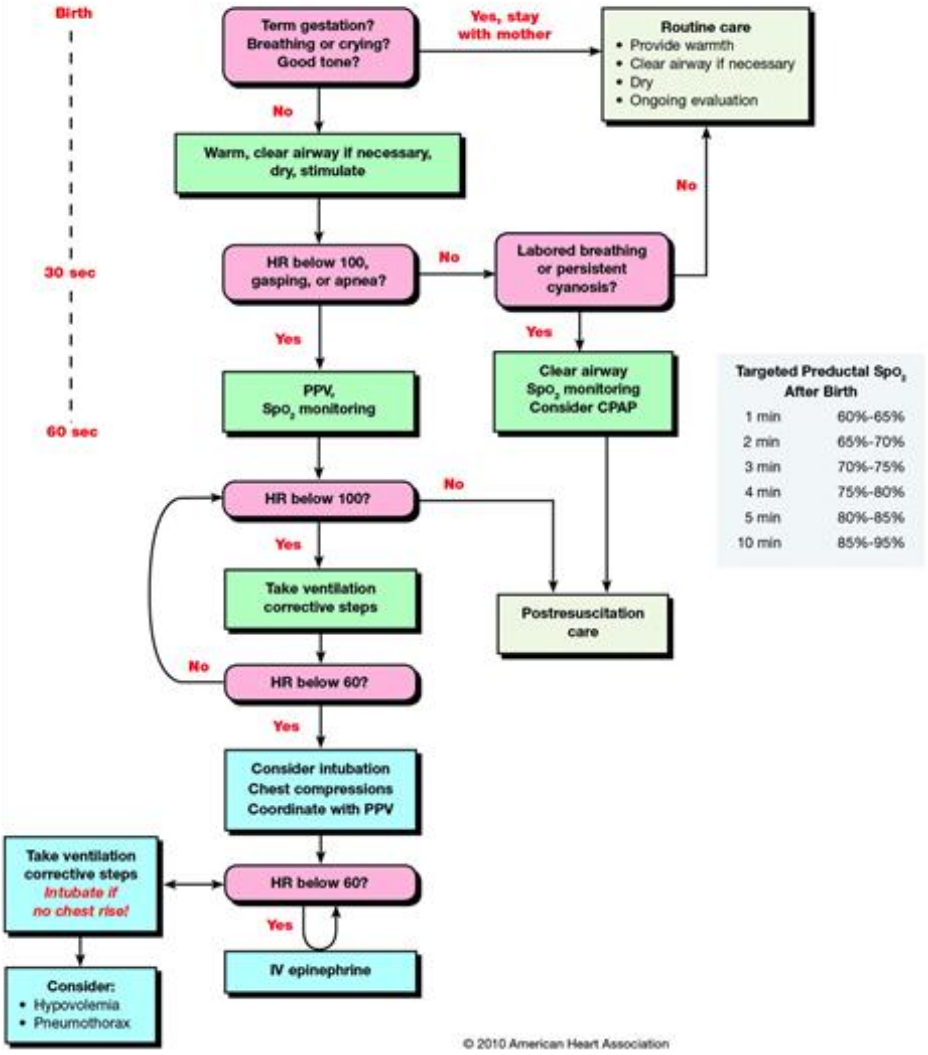
31. feroze, *neonatal resuscitation ;the use of laryngeal mask airway.* Professional medical journal, 2008. **15**: p. 148-52.

32. Micaglio, M., et al., *Training for neonatal resuscitation with the laryngeal mask airway: a comparison of the LMA-ProSeal and the LMA-Classic in an airway management manikin.* Paediatr Anaesth, 2006. **16**(10): p. 1028-31.

33. Berry, A.M., J.R. Brimacombe, and C. Verghese, *The laryngeal mask airway in emergency medicine, neonatal resuscitation, and intensive care medicine.* Int Anesthesiol Clin, 1998. **36**(2): p. 91-109.

34. Schmolzer, G.M., et al., *Supraglottic airway devices during neonatal resuscitation: An historical perspective, systematic review and meta-analysis of available clinical trials.* Resuscitation.

Newborn Resuscitation



ABBREVIATION

LMA=laryngeal mask airway

RCT =randomized control trial

AGA = appropriate for gestational age

LGA = large for gestational age

NRP= neonatal resuscitation programme

PPV= positive pressure ventilation

CPAP = continuous positive airway pressure

SGA = small for gestational age

FIO2 =fraction of inspired oxygen

ET = endotracheal tube

CDH =congenital diaphragmatic hernia

HIE =hypoxic ischemic encephalopathy

EOS = early onset sepsis

LOS =late onset sepsis

TTN = transient tachypnea of newborn

RDS = respiratory distress syndrome

CONSENT FORM

Title: Positive Pressure Ventilation During Neonatal Resuscitation In Neonates >34 Wks Gestation ;Efficacy Of LMA Vs Face Mask ; A Randomized Controlled Trial

I Ms/Mr._____ M/O//F/O, B/O _____

Sex_____Hosp. No._____ delivered in IOG,

Egmore on _____ was explained by the doctor that my baby may need positive pressure ventilation following delivery

I have read the patient information sheet and have been explained the nature of the study and I am aware of the following facts;

1) **I have been invited to allow my child to participate in a research project as mentioned above, because my child meets the eligibility criteria for the study .**

2) I have given my consent only after completely understanding the details that were explained to me.

3) I am willing for my baby to be enrolled in this study without any ones compulsion.

4) I am fully aware that I can withdraw from the trial at any time during the study and routine care will be continued.

5) If I give consent ,my child would be allocated to receive either ventilation with face mask or laryngeal mask airway provided my baby needs it.

6) I have also given my consent for drawing blood sample for biochemical analysis during the study if needed .

7) The rare complications which can arise was explained to me.

I have given this consent to be enrolled in this study with my full consciousness

Signature of the Investigator **Signature of parent**

Date :

Place: Chennai -8.

PATIENT INFORMATION SHEET

Title: Positive Pressure Ventilation During Neonatal Resuscitation In Neonates >34 Wks Gestation ;Efficacy Of LMA Vs Face Mask ; A Randomized Controlled Trial"

Majority of Neonates delivered require Routine Resuscitation (ie) drying and oral suction .Certain neonates require positive pressure ventilation (ie)giving artificial respiration when the baby is not breathing .Artificial respiration can be given by face mask applied over the face which is routinely followed .But due to the technical issues the amount of air reaching the lung with the device is compromised hence the chance for these neonates ending up in endotracheal intubation is high .Endotracheal intubation is highly technical and has its own disadvantages with the tube placed in the trachea causing more damage to the respiratory system.To overcome this problem researchers have started using Laryngeal mask airway (LMA)where the device is placed in to supraglottic area (area in the throat) .This device needs less technique for insertion and leads to effective ventilation (air reaching the lungs).Hence the chance for the neonates needing intubation may be low which needs to be proved by scientific studies.

This study is done with proseal type of LMA which has advantages when compared to classic LMA in terms of complications . Proseal type of LMA has gastric decompression port which will avoid gastric aspiration .In the present study we will include newborns which will require positive pressure ventilation during resuscitation. One group of newborns will receive facemask while the other will receive laryngeal mask airway .This is will be decided based on randomization method .

. You are being approached for enrolling your baby in this study . we will include your baby in the study only if you us a written consent . There is no compulsion. If you do not wish to enrol your baby in this study s/he will continue to get the standard treatment (ie)positive pressure ventilation with face mask

You can withdraw from the trial at anytime during the study. Your baby will continue to receive routine care given to an asphyxiated baby as per the hospital protocol. During the study, during the analysis of the results and during the publication of the study your identity will not be revealed.

The outcome of the study will be revealed to you after the completion of the study if requested for.

Signature of the Investigator Signature of Parent

Contact Address:
Dr.T. Ramesh kumar
II yr, D.M. Neonatology post graduate
I.C.H.&H.C, Egmore, Chennai- 8.
Mobile No.:9486961681.

Proforma

Patient IP no. _____

Group of Randomization: **Laryngeal Mask Airway (LMA)** □
Facial Mask (FM) □

Name _____ Date of birth _____

Antenatal history:
Gravida ___ Para___ Live birth ___ Maternal anemia, (yes/no) _____
Maternal hypertension/Preeclampsia, (yes/no) _____ Diabetes, (yes/no) _____
Placenta abruptio, (yes/no) _____ - Other, (specify) _____

Amniotic fluid: clear □ meconium stained □ - Other □, (specify) _____

Mode of delivery: vaginal □ Caesarean-section□
(reason): _____

Gestational age (wks)_____ Birth weight (g) _____

Reason for initiating PPV: Heart rate (HR)<100bpm □ Apnea □ Gasping□

Failure of PPV: yes □ no □
(HR<100bpm after 30 sec.)

Tracheal intubation yes □ no □

Reason for tracheal intubation: - failure of PPV with assigned device (LMA/FM) □
- need for prolonged ventilation for respiratory disease □
- other (specify)□

Postnatal age at intubation (sec.) _____ Chest compression yes □ no □

Duration of positive pressure ventilation_____(sec)

Time taken for insertion of the device_____(sec)

Time taken to reach Heart Rate > 100_____(sec)

No of attempts made to insert □

Apgar score 1min □ **5 min** □

Drugs: if yes, specify _____

Admission: level 2___ Neonatal intensive care unit (NICU) ___

Diagnosis at discharge: _____ Date _____

COMPLICATIONS: no □ yes □

- vomitus □
- regurgitation □
- pneumothorax □
- upper airway lesions □
- other□_____
- Breeastfeeding: yes □ (full __/ partial ___)
  no□

COMMENTS:

_____